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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,991	09/09/2003	Ridwan Shabsigh	0575/58075-Z/JPW/AJM/HA	4213

7590

09/13/2006

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EXAMINER

KELLY, ROBERT M

ART UNIT	PAPER NUMBER
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1633

DATE MAILED: 09/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/658,991	Applicant(s) SHABSIGH, RIDWAN	
	Examiner Robert M. Kelly	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9 and 10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response and amendment of 6/16/06 is entered.

Claims 9-10 are amended.

Claim 11 is cancelled.

Claims 9-10 are presently pending and considered.

Specification

In light of Applicant's amendments to the specification, the objections for not containing the status of the 09/234,591 Application, and for the length of the abstract, are withdrawn.

In light of Applicant's amendments to the specification, and submission of a proper sequence listing, the objections to the specification under 37 CFR 1.821-1.825, are withdrawn.

Claim Objections

In light of Applicant's amendment to Claim 10, the objection to such claim withdrawn.

Claim Rejections - 35 USC § 112 - Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-10 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, for reasons of record. The claim(s) contains subject matter

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which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Response to Argument – Enablement

Applicant's argument of 6/16/06 has been considered but is not found persuasive.

Applicant argues that co-submitted EXHIBIT C, a copy of Burchardt, et al. (2005) J. Urology, 66(3): 665-70, now made of record by the Examiner (attached Notice of References Cited), demonstrates that the claims are enabled, because the corpus cavernosa of rat penises were transformed and expressed VEGF 165 mRNA therefrom (pp. 9-10).

Such is not persuasive. First, the only reason for increasing/maintaining blood supply in the penis given in the specification is for the purpose of treating erectile dysfunction (See whole SPECIFICATION). Second, in accord with the argument given, vis-à-vis, the lack of predictability that such VEGF alone would increase vascularization and therefore blood supply, is further proven by Applicant's own publication (Burchardt, ABSTRACT and CONCLUSION). To wit, Burchardt states: "Although statistical trends were measured in the VEGF protein-treated group, no statistically significant difference in smooth muscle or endothelial cell content was found between control and VEGF-treated rats" (ABSTRACT). Further, the amount of smooth muscle cell and endothelial cell area is not different between protein and DNA transfer protocols (TABLE 1; p. 668, col. 2, paragraph 3). Lastly, even Burchardt teaches that VEGF likely requires other factors to act in concert and over time to provide angiogenic benefits (p. 668, col. 2, paragraph 3). Hence, if anything, Burchardt further supports the Examiner's position with regard to enablement.

Applicant argues that the amendments overcome causing increases in the endogenously-encoded VEGF production (pp. 10-11).

Such is persuasive, and overcomes that aspect of the rejection, but no other aspect.

Applicant attacks various aspects of each of the references of Verma, Eck, Deonarain, and Gorecki, to argue that the various aspects of enablement are not shown in those references (pp. 11-13).

Such is not persuasive. Given the teachings of each references, and their further support in the references of the state of the prior art, the Artisan would conclude that it was not reasonably predictable that any particular gene therapy would work. Moreover, the post-filing Burchardt reference provides clear evidence that levels of expression provided by the various aspects, as outlined in the references provided by the Examiner, are clearly important and critical to the enablement of the instantly claimed invention.

Applicant argues that their claims are drawn to increasing and/or maintaining the blood supply to the penis, and that Bivalacqua does not negate the claimed subject matter (p. 13).

Such is not persuasive. Applicant's only given purpose for such increasing/maintaining blood supply is to treat erectile dysfunction. Further, given the teaching of the specification, even if the Artisan were to find Applicant's general claim to encompass more than treating erectile dysfunction, it would still be understood to encompass treating erectile dysfunction, given the teachings throughout the specification. Hence, if Applicant wishes to only claim such, different claim language would be required to exclude treating erectile dysfunction. Next, even if it did somehow only encompass increasing/maintaining blood supply, the previous official action, and Burchardt, demonstrate that it is not reasonably predictable to do so. Lastly, broad

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aversion that Bivalacqua does not negate the enablement of the claims is not enough for the Examiner to answer, Applicant must specifically demonstrate how, so that a proper rebuttal or acquiescence may be given.

Applicant argues that Yancopoulos teaches that VEGF is critical for maintaining/increasing blood supply to a tissue, and therefore, does not negate the enablement of the claims (p. 13).

Such is not persuasive. Yancopoulos may recognize that VEGF is one of the major players in angiogenesis, but also recognizes that more is needed, and other reasons to doubt the efficacy of such VEGF treatment in angiogenesis in any particular tissue (Official Action of 1/13/06, pp. 13-14).

Applicant argues that the amendments overcome the enablement with respect those issues raised by Freed and Banerjee (pp. 13-14).

Such is persuasive. Those bases of the rejection for a vector contained within a nucleic acid are withdrawn.

Claims Free of the Prior Art

Claims 9-10 are free of the prior art of record.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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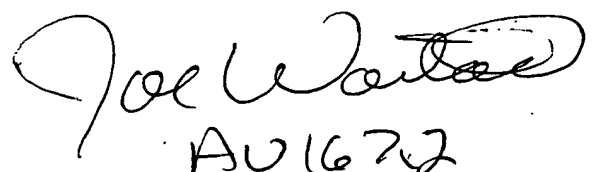
the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Kelly, Art Unit 1633, whose telephone number is (571) 272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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